



PharmaDan A/S

Quality Certificate

Product : LACTULOSE SOLUTION EP
Batch No. : Aca No. 21G01 / Our No. 1682-36
Quantity : 2160 x 5,0 liter

	<u>Analytical Data</u>	<u>Specifications</u>
Identification	Passes	Test B, C & D
LACTULOSE (w/v)	67.7%	> 62.0%
Related Substances (in % of the lactulose area)		
Lactose	Passes	< 10.0%
Galactose	Passes	< 15.0%
Tagatose	Passes	< 4.0%
Epilactose	Passes	< 10.0%
Fructose	Passes	< 1.0%
Methanol	* see below	< 30 ppm
Boron	* see below	< 5 ppm
Sulphite	Passes	<30 ppm
Specific Gravity, g/ml	1.331	
Appearance of Solution	Passes	10% w/v: < BY5 and clear
Sulphated Ash	Passes	< 0.2% of the lactulose content
Ph	5.4	3.0 – 7.0
TAMC	Passes	≤ 100/g
TYMC	Passes	≤ 10/g
E. Coli	Passes	≤ 1/g

* Neither Methanol nor Boron is used in the production of our Lactulose.
As a control measure Methanol and Boron are analyzed 4 times a year, once every quarter.

We confirm that this product is manufactured according to Good Manufacturing Practices

Date of Manufacture : July 2021
Date of Re-Test : July 2023
Date of Certificate : 14. July 2021
Conclusion : Batch accepted and released by Qualified Person

PharmaDan A/S

Qualified Person
Kjeld Johansen